

Arizona Medical Board

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DRAFT MINUTES FOR OFFICE BASED SURGERY COMMITTEE MEETING Held at 12:00 p.m. on August 10, 2005 9545 E. Doubletree Ranch Road · Scottsdale, Arizona

Office Based Surgery Committee Members

William R. Martin III. M.D. Ram R. Krishna, M.D. Douglas D. Lee, M.D.

CALL TO ORDER

William R. Martin III, M.D., Chair, called the meeting to order at 12:35 p.m.

ROLL CALL

The following Committee Members were present: William R. Martin III, M.D., Douglas D. Lee, M.D. and Ram R. Krishna,

CALL TO THE PUBLIC

There was no one present for Call to the Public.

NON-TIME SPECIFIC ITEMS Proposed Office Based Surgery Rules

Timothy C. Miller, J.D., Executive Director informed the Committee that the purpose of this meeting was to review the draft rules with the changes proposed at the July 16, 2005 Stakeholder meeting. Mr. Miller stated that the proposed rules makes clear what the Board's intent is for office-based surgery.

Mr. Miller informed the Committee that the Arizona Department of Health Services (ADHS) has concerns with the definition of general anesthesia as used in the rules. The DHS definition of general anesthesia is closer to deep sedation. ADHS agreed with the Board's definition, but had some concerns with measuring respiration. Once a facility is licensed with ADHS, all facilities must follow ADHS rules. Any physician using general anesthesia must be licensed by ADHS; however, ADHS only regulates the facility, not the physician. Once a physician performs general anesthesia it is within the Board's jurisdiction to regulate the physician in terms of quality of care. The ADHS standards will be in excess of the Board's standards of deep sedation. The physician will be required to do more than the Board would require. Mr. Miller and ADHS have worked out a schedule for coordinating each agency's rule drafting. By October 1, 2005 ADHS will have their ambulatory surgery rules drafted and will coordinate those rules with the Board's rules. By the end of the year, the agency will be able to submit a final set of revisions and have them to the Governor's Regulatory Review Counsel (GRRC) for review. The Board's rules will not state anything about the requirements of the facility. Mr. Miller reiterated that the Board's rules would set the standard of care and the minimum office requirements that would be needed to meet the standard of care. However, once a physician performs office based surgery using deep sedation, the ADHS rules would be much more stringent in terms of the facility.

Ram R. Krishna, M.D. stated that if the ADHS rules were more stringent than the Board's rules that would be fine. The Board would not fault a physician for not meeting the ADHS rules for the facility unless the problems with the facility presented a problem with the physician's care for the patient.

Mr. Miller clarified that the general statute states that the Board shall regulate facilities that are not licensed by ADHS. He and Ms. Cassetta will work together to determine what role the Board will play with non-ADHS licensed facilities. The statute authorizing the Board's rule relates to intravenous (IV) sedation only. It does not mention inhalation or conductive nerve block. However, these types of anesthesia are equally important as IV sedation because of the risks involved.

Ms. Cassetta stated that when the committee last edited the definition of office based surgery it included inhalation anesthesia and major conduction nerve blocks as part of the definition. The Committee might need to define inhalation anesthesia and major conduction nerve blocks separately.

The stakeholders present were asked to present their comments.

Mr. Larry Lanier from the American Academy of Dermatology spoke to the Committee. Mr. Lanier stated that the draft rules look good and he commended the Committee on the work involved putting these together. Mr. Lanier also thanked the Committee and staff for the courtesy extended to him during the informal public comments period.

Ms. Stacy Gaus from American Society of Nurse Anesthetists stated that the rules are going in a good direction. She added that her organization had specific language concerns that might result in unintended consequences. Throughout the rule, there are several places where it states, "The physician shall ..." This might put onerous requirements on the physician to be responsible for all the anesthetic monitoring and prevent nurse anesthetists from performing these duties.

Douglas D. Lee, M.D. responded to Ms. Gaus by stating that the physician is directly responsible for supervising staff and ensuring they are qualified. The Board has no jurisdiction over certified nurse anesthetists; however the physician is responsible for ensuring the nurse anesthetist is practicing according to accepted guidelines. Dr. Krishna agreed and stated that the physician would be responsible for supervising staff performing in an office based setting. Ms. Gaus recommended making the language more passive so that it is not so restrictive. William R. Martin, III, M.D. stated that he would like the physician to be held responsible for the patient's care. Ms. Cassetta clarified that the physician is responsible for ensuring the staff is properly trained and that staff carries out the appropriate procedures.

Dr. Lee stated that the choice of the anesthetic and the administration of the anesthetic is the physician's responsibility and the Board would hold the physician accountable for that choice.

Mr. Miller stated that the ADHS rules address the creation of a facility from the ground up. The Board's rules do not need to address OBS to the same degree, such as supervision.

Mr. Lanier asked if the Board would approve this draft at the August Board meeting. If so, will it be formally published and put out for public comment. Ms. Cassetta stated that in terms of process, after the Board's approval, the rules would be published in the Register and put out for public comment. Additional stakeholder input would be incorporated during the public comment period and the final rules would be brought back to the Board, with the public comments, for final approval. Mr. Lanier clarified that the final rules would not be formally published until the end of the year. Mr. Miller stated that the official public comment period would not begin until 2006.

Ms. Gaus asked about R4-16-707 (Equipment). She stated it would be more consistent to state, "the physician performing the following procedure" instead of the "supervising physician".

Dr. Lee asked if the order of the definitions could be changed. Ms. Cassetta stated that the definitions needed to be in alphabetical order, according to the Governor's Regulatory Review Counsel (GRRC) guidelines. Dr. Lee stated that conscious sedation is a term that is not commonly used. The term minimal sedation is appropriate.

Dr. Lee also referred to R4-16-702. He stated that the content is scattered and it is hard to understand the meaning. He suggested changing this language when the rules go out for public comment. Under R4-16-703 (B)(5) Dr. Lee pointed out that where it states "evaluate ventilation adequacy by continued observation and qualitative clinical signs...during general anesthesia and monitored anesthesia care" that one can monitor CO2 in an awake sedated patient, but monitored anesthesia care was not defined anywhere. Ms. Gaus stated that her organization also noticed this language and that it was not an issue, but they did not know where the language came from. Dr. Lee stated that it might be in the American Society of Anesthesiologists (ASA) language. Ms. Cassetta recommended deleting the language after "during general anesthesia." The Committee agreed that monitored anesthesia care should not be included under the general anesthesia section.

Dr. Lee stated that under R4-16-707 an Fi02 monitor is not required for physicians who do not perform general anesthesia. It is used only when general anesthetic is applied. Ms. Cassetta stated that language could be moved to another section of the rules.

The Committee agreed to bring the draft rules forward, with the changes made at this meeting, to the Board tomorrow.

Approval of Minutes

MOTION: Douglas D. Lee, M.D. moved to approve the August 3, 2005 Office Based Surgery Minutes.

SECONDED: Ram R. Krishna, M.D.

VOTE: 3-0

MOTION: Ram R. Krishna, M.D. moved to approve draft rules and forward them to the Board for review.

SECONDED: Douglas D. Lee, M.D.

VOTE: 3-0

The meeting adjourned at 1:06p.m.

[Seal]

Timothy C. Miller, J.D., Executive Director